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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,697	09/27/2001	Tarlochan Singh Dhadialla	2584.0270002/RWE/GER	4412
80011	7590	05/25/2010	EXAMINER	
Sterne, Kessler, Goldstein & Fox P.L.L.C. 1100 New York Avenue N.W. Washington, DC 20005			SHAFER, SHULAMITH H	
		ART UNIT	PAPER NUMBER	
		1647		
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		05/25/2010	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/965,697	DHADIALLA ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	SHULAMITH H. SHAFER	1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 23 March 2010.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-4, 7, 9, 10, 12 and 50-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-4, 7, 9, 10, 12 and 50-54 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>23 March 2010 and 21 April 2010</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: _____ .                        |

### **Detailed Action**

#### ***Status of Application, Amendments, And/Or Claims:***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 23 March 2010 has been entered.

Applicants' amendment of 23 March 2010 is acknowledged. Claims 8, 15, 25-46, 48 and 49 have been canceled. Claims 1, 2, 9 and 10 have been amended and amendment made of record. Claims 50-54 are newly presented and made of record.

Claims 1-4, 7, 9, 10, 12 and 50-54 are pending and under consideration in the instant application.

It is noted that in a telephone interview on 1 March 2010 with Applicants' representative, a terminal disclaimer over copending SSN 11/841,325 was discussed. SSN 11/841,325 was expressly abandoned on 24 March 2010. The issue of nonstatutory double patenting is thereby moot.

#### ***Information Disclosure Statement:***

The Information Disclosure statements (IDS) submitted on the 23 March 2010 and 21 April 2010 have been considered. The signed copies are attached.

### **Withdrawn Rejections**

Claims 5, 6, 8, 11, 15, 48 and 49 have been canceled; all objections and rejections of these claims are thereby moot.

The rejection of claims 1-4, 7, 9, 10, and 12 as failing to comply with written description requirement is withdrawn in light of Applicants amendment of the claims.

## New Grounds of Rejection

### Rejections

#### **35 U.S.C. § 112, Second Paragraph:**

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 7, 9, 10, 12 and 50-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in reciting, at section a):

“i) a polynucleotide encoding a receptor complex comprising:  
A) a DNA binding domain;  
B) an ecdysone receptor ligand binding domain and a nuclear receptor ligand binding domain capable of forming a dimer with the ecdysone receptor ligand binding domain; and  
C) a transactivation domain;”

It is unclear if Applicants intend a **single polynucleotide** to encode a single chimeric polypeptide comprising a DNA binding domain, an ecdysone receptor ligand binding domain, a second nuclear receptor ligand binding domain and a transactivation domain or a **first polynucleotide** encoding a polypeptide comprising a DNA binding domain and an ecdysone receptor ligand binding domain and a **second polynucleotide** encoding a second polypeptide comprising a nuclear receptor ligand binding domain capable of forming a dimer with the ecdysone receptor ligand binding domain and a transactivation domain or a **first polynucleotide** encoding a polypeptide comprising a DNA binding domain, an ecdysone receptor ligand binding domain and a second nuclear receptor ligand binding domain and a **second polynucleotide** encoding a polypeptide encoding a transactivation domain or something else entirely.

Claim 2 is indefinite in reciting, at section b):

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"b) i) a first gene expression cassette comprising a polynucleotide that encodes a polypeptide comprising a transactivation domain, a DNA-binding domain that recognizes a response element associated with a gene whose expression is to be modulated; and an *ecdysone\_receptor ligand binding domain*,

ii) a nuclear receptor ligand binding domain selected from the group consisting of a vertebrate retinoid X receptor ligand binding domain, an invertebrate retinoid X receptor ligand binding domain, an ultraspiracle protein ligand binding domain, and a chimeric ligand binding domain comprising two polypeptide fragments, wherein the first polypeptide fragment is from a vertebrate retinoid X receptor ligand binding domain, an invertebrate retinoid X receptor ligand binding domain, or an ultraspiracle protein ligand binding domain, and the second polypeptide fragment is from a different vertebrate retinoid X receptor ligand binding domain, invertebrate retinoid X receptor ligand binding domain, or ultraspiracle protein ligand binding domain"

It is unclear if Applicants intend ***a single polynucleotide*** to encode a single chimeric polypeptide comprising a transactivation domain, a DNA-binding domain, an *ecdysone\_receptor ligand binding domain* and a second nuclear receptor ligand binding domain or ***a first polynucleotide*** encoding a polypeptide comprising a transactivation domain, a DNA-binding domain and an *ecdysone\_receptor ligand binding domain* and ***a second polynucleotide*** encoding a polypeptide comprising a second nuclear receptor ligand binding domain.

Claim 9 is vague and indefinite in reciting, at section a):

"i) a receptor complex comprising:  
A) a DNA binding domain;  
B) an *ecdysone receptor ligand binding domain* and a nuclear receptor ligand binding domain capable of forming a dimer with the *ecdysone receptor ligand binding domain*; and  
C) a transactivation domain;"

It is unclear if the receptor complex comprises ***a single polypeptide*** comprising a DNA binding domain, an *ecdysone receptor ligand binding domain*, a nuclear receptor ligand binding and a transactivation domain or ***a first polypeptide*** comprising a DNA binding domain and an *ecdysone receptor ligand binding domain* and ***a second***

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**polypeptide** comprising a second nuclear receptor ligand binding domain and a transactivation domain or some other combination of polypeptides.

The Examiner requires clarification as the disclosure teaches only the following working examples:

"A polynucleotide encoding the C, D, E, and F domains from fruit fly *Drosophila melanogaster* EcR ("DmEcR-CDEF"; SEQ ID NO: 1) was fused to a polynucleotide encoding a GAL4 DNA binding domain ("Gal4DNABD" or "Gal4DBD"; SEQ ID NO: 2) and placed under the control of a cytomegalovirus (CMV) promoter/enhancer (SEQ ID NO: 3). A polynucleotide encoding the C, D, E, and F domains from spruce budworm *Choristoneura fumiferana* EcR ("CfEcR-CDEF"; SEQ ID NO: 4) was fused to a polynucleotide encoding a LexA DNA binding domain ("LexADNABD" or "LexADBD"; SEQ ID NO: 5) and placed under the control of a cytomegalovirus (CMV) promoter/enhancer (SEQ ID NO: 3). A polynucleotide encoding a chimeric EF domains polypeptide from mouse *Mus musculus* retinoid X receptor isoform .alpha. ("MmRXR.alpha.") and locust *Locusta migratoria* ultraspiracle protein ("LmUSP-EF") (SEQ ID NO: 6) was fused to a polynucleotide encoding a transactivation domain from VP16 ("VP16AD"; SEQ ID NO: 7) and placed under the control of a CMV promoter/enhancer (SEQ ID NO: 3) [paragraph 0282]. A polynucleotide encoding the C, D and E domains from green leafhopper *Nephotetix cincticeps* ecdysone receptor ("NcEcR-CDE"; SEQ ID NO: 15) was fused to a polynucleotide encoding a GAL4DNA binding domain ("GAL4DBD"; SEQ ID NO: 2) and placed under the control of a cytomegalovirus (CMV) promoter/enhancer (SEQ ID NO: 3). A polynucleotide encoding the E and F domains from mouse *Mus musculus* retinoid X receptor isoform .alpha. ("MmRXR.alpha.); SEQ ID NO: 16) was fused to a polynucleotide encoding a transactivation domain from VP16 ("VP16AD"; SEQ ID NO: 7) and placed under the control of a CMV promoter/enhancer (SEQ ID NO: 3) [paragraph 0283].

Thus, the only working examples are directed to polynucleotides encoding polypeptides comprising a DNA binding domain, and an ecdyson ligand binding domain and polynucleotides encoding transactivation domain and a chimeric RXR-USP ligand

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binding domain. There are no examples, working or prophetic, of polynucleotides encoding, for example, chimeric polypeptides comprising an ecdysone ligand binding domain and a second ligand binding domain.

***Conclusion:***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHULAMITH H. SHAFFER whose telephone number is (571)272-3332. The examiner can normally be reached on Monday through Friday, 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D. can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shulamith H. Shafer/  
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